

10/021,407
END0795USNPRemarks

Claims 5-8 and 13-18 were rejected. Claim 15 has been amended. All of the amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved. Because the Office Action dated 01/24/2006 was Final, this amendment is being filed contemporaneously with a Request for Continued Examination (RCE).

Claims 5, 8, 13-15, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. (U.S. Pat. No. 3,606,878) in view of Van Vaals (U.S. Pat. No. 6,430,429). Claims 6 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. in view of Van Vaals and further in view of Gillies et al (U.S. Pat. No. 6,272,370). Claims 7 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kellogg, Jr. in view of Van Vaals and further in view of Werne (U.S. Pat. No. 5,782,764). Applicant respectfully traverses these rejections.

Under MPEP 2143, in order to establish a *prima facie* case of obviousness, the prior art reference or combination of references must teach or suggest all of the limitations of a claim. A *prima facie* case of obviousness also requires that there be some teaching suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In view of the foregoing requirements for a *prima facie* case of obviousness, Applicant submits that the combined art of record fails to render the amended claims obvious. In particular, Applicant notes that the combination of references fails to teach or suggest all of the limitations of each amended independent claim in accordance with MPEP 2143.03. In addition, Applicant submits that even if the combined art of record taught or suggested all of the limitations of each present independent claim, there is no teaching, suggestion, or motivation to modify or combine the references to obtain the invention presently claimed,

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such that a *prima facie* case of obviousness has not been, and cannot be, established in accordance with MPEP 2143.01.

Each of the present independent claims (claim 5, claim 14, and amended claim 15) recites that the material that will leave an artifact is spaced distally from the side port of a needle. The combined art of record fails to teach or suggest such limitations. In other words, to the extent that the combined art of record teaches or suggests using such material, the combined art of record fails to teach or suggest the particular recited location for such material (i.e. spaced distally from the side port of a needle). The combined art of record therefore fails to render any of the independent claims obvious in accordance with MPEP 2143.03. Applicant therefore respectfully requests that the rejections be withdrawn.

Furthermore, even if the combined art of record taught or suggested all of the elements of any of the independent claims, the art is devoid of any suggestion or motivation to modify or combine the teachings of the references in order to obtain the claimed invention. Indeed, MPEP 2143.01 admonishes that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (emphasis in original). *Actual evidence* of a suggestion, teaching, or motivation to combine or modify prior art references must be shown. *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999). To the extent that the combined art of record provides motivation to use a material that will leave an artifact, there is no motivation to provide such material in the particular location recited in the claims (i.e., spaced distally from the side port of a needle). Even if the prior art provided motivation to provide such material generally near the distal end of an apparatus, which Applicant does not admit, such motivation does not amount to specific motivation to provide the material spaced distally of the side port of a needle in addition to the remaining limitations recited in the claims. At most, and without admitting that the presently claimed combinations would have been obvious to try, such general guidance in the prior art would only make the presently claimed combinations "obvious to try," which is insufficient for a *prima facie* case of obviousness under MPEP 2145. Because the evidence of motivation required by MPEP 2143.01 is lacking, Applicant respectfully requests that the rejection be withdrawn.

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Beyond the foregoing shortcomings with respect to the rejections of the independent claims, Applicant further notes that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for novelty and non-obviousness.

To the extent that the present amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. While Applicant has noted several distinctions over the art of record, Applicant notes that several other distinctions exist, and Applicant preserves all rights and arguments with respect to such distinctions.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,407	12/12/2001	Edward A. Rhad	END-795	3685

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,407

Applicant(s)

RHAD ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5, 8, 13, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals.

In regards to claims 5, 8, 13, 14, 15 and 18, Kellogg, Jr. discloses a biopsy device (Figure 1) including an elongated substantially tubular needle having a distal end (12), a proximal end, a longitudinal axis there between, a cutter lumen (Col. 2, lines 43 - 44), a non-metallic liner (20) extending along a portion of the cutter lumen; a vacuum lumen (14), a side port (10b) for receiving a tissue sample (Col. 3, lines 55 - 56); a sharpened distal tip for insertion within tissue (Col. 3, lines 45 - 49), the sharpened distal tip attached to the distal end of the needle and a cutter (24) movable within the cutter lumen (Col. 2, lines 62 - 64). However, Kellogg, Jr. fails to disclose the needle being non-metallic and the distal tip having a cavity in which an artifact creating material is disposed. Van Vaals discloses a non-metallic biopsy needle (Col. 6, lines 55 - 60) including a distal tip (6; Figure 2) having a cavity in which an artifact creating material is disposed (Figure 3; Col. 6, line 61 - Col. 7, line 34). Van Vaals discloses the artifact creating material as being selected from the group of gadolinium, titanium, aluminum, copper, brass and bronze (Col. 7, lines 1 - 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy needle as disclosed by Kellogg, Jr. to be non-metallic and to include a distal tip having a

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cavity in which an artifact creating material is disposed as taught by Van Vaals in order to track the needle within the body of the patient so as to guide the needle safely through the body without damaging the tissue and to guide the needle to the desired position (Col. 2, lines 41 – 50).

3. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 6,272,370 to Gillies et al.

In reference to claims 6 and 16, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a thermoplastic. However, Gillies et al. discloses an MRI compatible device formed of a non-metallic material including a thermoplastic (Col. 24, lines 17 – 19). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a thermoplastic as taught by Gilles et al. or any MRI compatible material as desired.

4. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claims 7 and 17, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a glass fiber reinforced polymer resin. However, Werne discloses an

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MRI compatible device including a needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a glass fiber reinforced polymer resin as taught by Werne or any MRI compatible material as desired.

Response to Arguments

5. Applicant's arguments filed 10/13/05 have been fully considered but they are not persuasive. Applicant asserts that the Examiner has not shown the required motivation in the prior art to modify Kellogg, Jr. by the teaching of Van Vaals and that the combination suggested by the Examiner is based on improper hindsight reliance of Applicant's invention. However the Examiner disagrees. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, Kellogg, Jr. teaches a standard biopsy needle. Van Vaals teaches an improved biopsy needle (Col. 6, lines 55 – 57) being formed of a non-metallic material and having a cavity in the distal tip in which an artifact inducing material is placed (Col. 6, line 64). Van Vaals teaches that such a biopsy needle is beneficial because it allows introduction of the needle into a patient while being guided by magnetic resonance imaging. The Examiner has used such a teaching as the motivation to modify the needle as disclosed by Kellogg, Jr. with the teachings of Van Vaals. The

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Examiner maintains that the motivation to modify the prior art to arrive at the present invention has come from the references themselves and renders the claims unpatentable under 35 U.S.C. 103(a) over Kellogg, Jr. in view of Van Vaals.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

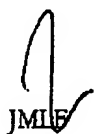
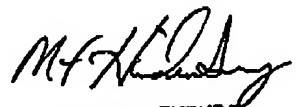
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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